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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,778	08/02/2004	Muhammed Majeed	108064-00196	4777

4372 7590 12/24/2008
ARENT FOX LLP
1050 CONNECTICUT AVENUE, N.W.
SUITE 400
WASHINGTON, DC 20036

EXAMINER

LEITH, PATRICIA A

ART UNIT	PAPER NUMBER
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1655

NOTIFICATION DATE	DELIVERY MODE
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12/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary	Application No. 10/710,778	Applicant(s) MAJEED ET AL.	
	Examiner Patricia Leith	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-17 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-17 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/2008 has been entered.

Claims 11-17 and 20-24 are pending in the application and were examined on their merits.

Applicants' arguments in light of the claim amendments were sufficient to overcome the previous rejections made under 35 USC 103(a) as well as under Double patenting. Said rejections are hereby removed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-17 and 20-24 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 11 has been amended to recite 'about 400mg boswellic acid' and 'about 100 micrograms of selenomethionine.' The terms 'about' in these phrases were not originally disclosed in this application as filed and are thus considered New Matter. The term 'about' changes the scope of the amount of boswellic acid and selenomethionine to amounts outside of 400mg and 100 mcg respectively; such amounts not having been contemplated at the time the Invention was made.

Claim 11 has further been amended to recite 'comprising 5% w/w Boswellia serrata extract comprising boswellic acid.' However, the disclosure, as originally filed does not appear to disclose any Boswellia extract containing boswellic acid; rather, the original disclosure as filed teaches a Boswellia serata gum resin extract containing beta-boswellic acid, acetyl-beta-boswellic acid, 11-keto-beta-boswellic acid and Acetyl-11-keto-beta-boswellic acids ([0060] for example). Hence, the New Matter is two-fold in this new amendment, first, it does not appear that an extract of any plant part, or the

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entire plant of *Boswellia serrata* was contemplated at the time of filing, save for an extract from the gum resin, and secondly, it does not appear that Applicants contemplated an extract from *Boswellia serrata* containing any boswellic acid. The boswellic acid referred to in this claim can be directed toward any derivative of boswellic acid which was not contemplated at the time the Invention was made.

Claims 12, 21, 23 and 24 all recite 'about 400mg boswellic acid' and 'about 100 micrograms of selenomethionine.' The terms 'about' in these phrases were not originally disclosed in this application as filed and are thus considered New Matter. The term 'about' changes the scope of the amount of boswellic acid and selenomethionine to amounts outside of 400mg and 100 mcg respectively; such amounts not having been contemplated at the time the Invention was made.

Claims 21, 23, and 24 all recite 'comprising 5% w/w *Boswellia serrata* extract comprising boswellic acid.' However, the disclosure, as originally filed does not appear to disclose any *Boswellia* extract containing boswellic acid; rather, the original disclosure as filed teaches a *Boswellia serrata* gum resin extract containing beta-boswellic acid, acetyl-beta-boswellic acid, 11-keto-beta-boswellic acid and Acetyl-11-keto-beta-boswellic acids ([0060] for example). Hence, the New Matter is two-fold in this new amendment, first, it does not appear that an extract of any plant part, or the entire plant of *Boswellia serrata* was contemplated at the time of filing, save for an extract from the gum resin, and secondly, it does not appear that Applicants

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contemplated an extract from *Boswellia serrata* containing any boswellic acid. The boswellic acid referred to in this claim can be directed toward any derivative of boswellic acid which was not contemplated at the time the Invention was made. Thus, while it appears that Applicants are attempting to amend the claims in accordance with what was shown in the Declaration to have unexpected results as submitted by Dr. Majeed on 3/07/2008, the *Boswellia serrata* extract of the Declaration, which states 'Boswellia serrata extract (400 mg boswellic acids)' is not specifically disclosed in the specification. Applicants may not import limitations from the declaration into the claims which were not originally disclosed.

Claims 22 and 23 recite 'derivatives of selenomethionine' and 'derivatives of Se-methylselenocysteine' which are not found in this application as originally filed.

Applicants have not pointed out where in the disclosure these phrases can be found, and upon careful review of the disclosure as filed, the Examiner cannot determine that Applicants were in possession of the breadth of any selenomethionine derivative or any Se-methylselenocysteine compound. The disclosure of several compounds which may meet the description of 'derivatives of selenomethionine' and 'derivatives of Se-methylselenocysteine' does not provide evidence of conception of the entire genus of derivatives absent sufficient indication that Applicants' disclosure is consistent with the disclosure of the genus of these derivatives.

Because claims 13-17 and 20 are all directly or indirectly dependent upon a claim which comprises New Matter, these claims also necessarily contain New Matter and are properly rejected under this statute.

The claims are free of the art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

/Patricia Leith/
Primary Examiner, Art Unit 1655